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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,405	11/20/2003	Joo Hwan Yang	1942/55	5538

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KENYON & KENYON LLP
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WASHINGTON, DC 20005

EXAMINER

SHEIKH, HUMERA N

ART UNIT	PAPER NUMBER
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1615

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/716,405	YANG, JOO HWAN	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

Receipt of the Certified Copy of Foreign Priority Documents filed 11/20/03 is acknowledged.

Claims 1-4 are pending in this action. Claims 1-4 are rejected.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, line 3, part (iii) recites the limitation, “*adding a small amount...*”. The phrase “a small amount” is indefinite because it is rather vague and relative. The phrase “a small amount” is unclear in the sense that it does not set forth and establish any upper and lower limits of the ingredients. Clarification is requested.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,410,050 B1 ('050 Patent) in view of Hansen *et al.* (U.S. Patent No. 6,423,346 B1). Although the conflicting claims are not identical, they are not patentably distinct from each other because similar subject matter has been claimed in both the instant application and the '050 Patent.

The only distinction observed between the instant claims and that of the '050 Patent is that the instant claims are drawn to a process for preparing a *fish gelatin* capsule whereas the '050 Patent is drawn to a process for preparing a *cellulose* capsule. However, both the instant claims and the '050 Patent entail a similar process comprised of similar components for preparing the capsules. Namely, both the instant application and the '050 Patent claim the

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following steps: (i) preparing a mixed solution of pectin and glycerin; (ii) adding the mixed solution to the solubilized fish gelatin (instant claims) or cellulose solution ('050 Patent); (iii) adding calcium gluconate, sucrose fatty acid esters and glacial acetic acid to said mixture and (iv) allowing the mixture to stand to adjust viscosity and forming the capsule there from. These steps are essentially similar in both the instant application and the '050 Patent. It is noted that the instant application claims the additional forming steps, such as dipping the mold pin; molding the film, cooling said film, etc. However, the processes for formation of the capsules in the instant application and the '050 Patent are essentially the same.

It is noted that the instant claims are drawn to a process for preparing a *fish gelatin* capsule whereas the '050 Patent is drawn to a process for preparing a *cellulose* capsule. Nonetheless, it would have been obvious to one of ordinary skill in the art to formulate either a fish gelatin capsule or a cellulose capsule comprising cellulose derivatives. Hansen *et al.* (USPN 6,423,346 B1) is relied upon for the teaching of a fish gelatinous composition for use as an ingredient in tablets, whereby, in addition to fish gelatin, the fish gelatinous protective colloid may comprise chemically modified hydrocolloids, such as cellulose derivatives, including methyl cellulose, carboxymethyl cellulose and hydroxypropyl cellulose (see column 3, lines 43-67).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to formulate a fish gelatin capsule which additionally incorporates cellulose derivatives because Hansen *et al.* teach that a fish gelatin capsule which comprises beneficial ingredients that include cellulose derivatives. The expected result would be an improved gelatin capsule that offers enhanced benefits and properties.

Pertinent Art:

Prior Art made of record and cited of interest:

■ Hansen *et al.* (USPN 6,423,346) :

Hansen *et al.* teach a fish gelatin capsule comprising fish gelatinous protective colloid. The capsule may comprise additional ingredients, such as pectin, fatty acids and derivatives thereof and glycerin. The capsule can have use in dietary applications (see column 1, lines 4-26); (col. 3, line 43 – col. 4, line 22).

■ Apfel *et al.* (EPO 0 346 879) :

Apfel *et al.* teach water insoluble drugs coated by coacervated fish gelatin to form microparticles (see column 2, lines 14-23) and Abstract.

Conclusion

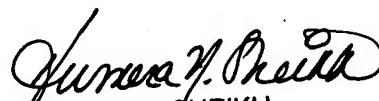
■ No claims are allowed at this time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


HUMERA N SHEIKH
PRIMARY EXAMINER

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February 28, 2007

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